

CERTIFICATE OF ELECTRONIC TRANSMISSION

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November 19, 2007
Date

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Edwin J. Hlavka et al.
Ser. No.: 10/622,207
Filed: July 18, 2003
Group Art No.: 3739
Examiner: William H. Matthews
For: METHOD AND APPARATUS FOR PERFORMING CATHETER-
BASED ANNULOPLASTY
Confirmation No.: 4023
Atty Ref.: MICO-06C

Cincinnati, Ohio 45202

November 19, 2007

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Sir:

RESPONSE

This is in response to the non-final Office Action mailed May 21, 2007.

Claims 60-67 and 69 are pending. In that non-final Office Action, the Examiner rejected claims 60-67 as allegedly being anticipated by Kuehn et al., U.S. Patent Publication No. 2004/0167539 (the Kuehn '539 publication). The Examiner failed to indicate any action on claim 69. Therefore, Applicants respectfully request such action in the next communication.

In rejecting claims 60-67, the Examiner simply referred to paragraphs 0076-0078, 0087-0090, and 0120, as well as Figures 8-11, of the Kuehn '539 publication. The Examiner alleged that the Kuehn '539 publication discloses:

. . . a device for use in annuloplasty procedures comprising plurality of non-plicating fasteners, catheter having guidewire, elongate tensioning element connecting the fasteners having a locking knot feature, and expandable members ("jaws") capable of being expanded against tissue.

Independent claim 60 requires "a plurality of non-plicating fasteners configured to be individually fixed to tissue adjacent the annulus of the heart valve at spaced locations."

Contrary to this, the Kuehn '539 publication discloses a pair of barbed needles 200 that are configured to be fixed to edges of the valve leaflets 122, 124 as clearly shown in Fig. 8 and described in the sections of the Kuehn '539 publication referred to by the Examiner. Therefore, the Kuehn '539 publication clearly fails to disclose fasteners as set forth in claim 60.

In addition, claim 60 requires "an elongate tensioning element coupled with the plurality of non-plicating fasteners and configured to be tensioned by pulling on only one end thereof to place the plurality of non-plicating fasteners in an activated state positioned closer together to plicate the tissue between the fasteners." Even if the barbed needles 200 and suture element 206 fixed therebetween were fastened or fixed to tissue adjacent a valve annulus, the suture 206 of Kuehn et al. is clearly not coupled with the barbed needles 200 in a manner that allows a surgeon to pull on only one end thereof to bring the barbed needles closer together and plicate tissue therebetween.

Clearly contrary to this, in paragraph 0088, the Kuehn '539 publication merely discloses that the barbed needles 200 are "connected to each other by suture 206." The barbed needles 200 may not be brought closer together in the claimed activated state by pulling on only one end of the suture 206. Indeed, the suture 206 is fixed on each end to the respective barbed needles 200. In the alternative embodiment referred to by the Examiner in Fig. 11 of the Kuehn '539 publication, each barbed needle 222 has a wire

224 extending therefrom and a suture 226 connects the two wires 224. A push rod 210 is disclosed as being rotated to "wind suture 226 and ultimately to wind wires 224."

Paragraph 0089 of the '539 publication goes on to state that "[t]he winding of wires 224 draws barbed needles 222 closer together, resulting in leaflets 122, 124 being drawn closer together." This clearly refers to the suture being twisted at a midpoint between the two barbed needles, thereby twisting the two wires, and bringing the barbed needles and leaflets closer together. This disclosure fails to anticipate the recitation in claim 60 requiring that the elongate tensioning element be coupled with the plurality of non-plicating fasteners and "configured to be tensioned by pulling on only one end thereof to place the plurality of non-plicating fasteners in an activated state positioned closer together to plicate the tissue between the fasteners." For at least these reasons, the '539 publication fails to anticipate independent claim 60 and its dependent claims 61-67, and the rejection should be withdrawn.

If the Examiner believes any matter requires further discussion, the Examiner is respectfully invited to telephone the undersigned attorney so that the matter may be promptly resolved.

Applicants do not believe that any fees are due in connection with this response other than the extension fee. However, if such petition is due or any fees are

necessary, the Commissioner may consider this to be a request for such and charge any necessary fees to deposit account 23-3000.

Respectfully submitted,

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